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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,698	05/14/2001	John M. Kirwan	F0397/7050	3328

7590

06/03/2003

Timothy J Oyer
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EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,698

Applicant(s)

KIRWAN ET AL.

Examiner

Roz Ghafoorian

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3--57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,3, 5-8, 15-19, 20-46, 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No.5766157 to Tilton Jr.

Tilton teaches a surgical device comprising of a cannula 25 an applicator 31 with an open tube, and a snap-fit ball and socket joint 37, limited orifice 112A, with a third unit 112, with all the units irremovably attached to each other.

1. Claims 1, 3-4, 9-11,15, 20-45 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent No.6146373 to Cragg et al.

Cragg teaches a surgical device with a cannula 48, an applicator 46, and an adaptor 38. The catheter injects a liquid forming a solidification agent.

2. Claims 1, 15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent No.6248092 to Miraki et al.

Miraki teaches a device with a cannula 20 and an applicator 12, the device can be sterilized via autoclave. (Col.3, lines 50-55)

3. Claims 1, 12-13, 20-45, 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No.5817072 to Lampropoulos et al.

Lampropoulos teaches a surgical device with a cannula section 24 and an applicator section 14, where the cannula has a radio-opaque marker 280 molded in the one of the modules. (Col.16, lines 55-60) method of conducting the device comprises accessing a treatment site with a first device 10, through a cannula 12 wherein the first device is a single component device, and device can deliver therapeutic agent via lumen 38 to the treatment site via the first device, then a tube 14 is added to the device altering the first device to the second device and the second device can also deliver therapeutic agent to the site via lumen 38. (Col.6, lines 15-20, Col.7, lines 1-10)

Response to Arguments

4. Applicant's arguments filed 3-31-2003 have been fully considered but they are not persuasive.

a. The applicant alleges Tilton lacks two or more modular units at least one of which is capable of being interchanged during surgery or a joint that facilitates rotating movements. However the applicant has defined "modular" as standardized units or sections, which are easily, attached and detached from

each other. (Page 5, lines 24-25) hence with the definition the applicant has given modular Tilton does teach units or sections such as 112 and 114 where at least one section or unit 112 can be interchanged during surgery. Tilton also teaches a joint 132, 109 wherein the rotational movement may be at least 90, 180 and 360 degrees.

b. The applicant alleges Cragg fails to teach an applicator section for delivery a fluid, the applicant alleges distal end cap 46 does not allow exit of fluid and hence it may not be considered an applicator. However distal end cap 46 contains a hole which allows tube 14 to pass through hence distal end cap does allow for the exit of fluid, therefore it may be consisted an applicator as the applicant has defined applicator.

c. The applicant alleges Miraki fails to teach two or more module units at least one of which is capable of being interchange during surgery. However the applicant has defined "modular" as standardized units or sections, which are easily, attached ant detached from each other. (Page 5, lines 24-25) hence with the definition the applicant has given modular Miraki does teach units 210 or 114 and 82, at least one of the modules 82 is capable of being interchanged during surgery.

d. The applicant alleges Lampropoulos fails to teach two or more module units at least one of which is capable of being interchange during surgery. However the applicant has defined "modular" as standardized units or sections, which are easily, attached ant detached from each other. (Page 5, lines 24-25)

hence with the definition the applicant has given modular Lampropoulos does teach units 43 and 24, at least one of the modules 24 is capable of being interchanged during surgery.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
May 30, 2003

A handwritten signature in black ink, appearing to read "Michael J. Hayes". The signature is written in a cursive, flowing style.

**MICHAEL J. HAYES
PRIMARY EXAMINER**